

BEFORE THE DEPARTMENT OF PUBLIC  
HEALTH AND HUMAN SERVICES OF THE  
STATE OF MONTANA

In the matter of the amendment of       ) NOTICE OF AMENDMENT  
ARM 37.112.103, 37.112.108,       )  
37.112.109, 37.112.116, 37.112.117,       )  
37.112.131, 37.112.133, 37.112.137,       )  
37.112.142, 37.112.144, 37.112.147,       )  
37.112.158, 37.112.159, and       )  
37.112.167 pertaining to body art and       )  
cosmetics       )

TO: All Concerned Persons

1. On November 8, 2012, the Department of Public Health and Human Services published MAR Notice No. 37-615 pertaining to the public hearing on the proposed amendment of the above-stated rules at page 2264 of the 2012 Montana Administrative Register, Issue Number 21.

2. The department has amended ARM 37.112.108, 37.112.116, 37.112.137, 37.112.142, 37.112.144, 37.112.158, 37.112.159, and 37.112.167 as proposed.

3. The department has amended the following rules as proposed, but with the following changes from the original proposal, new matter underlined, deleted matter interlined:

37.112.103 DEFINITIONS (1) through (7) remain as proposed.

(8) "Cleaning room" means the room used to sterilize instruments and jewelry with an autoclave.

(8) through (14) remain as proposed, but are renumbered (9) through (15).

~~(15) (16) "Implant" means an artificial object inserted into a person's body. Implants do not include microdermal anchors or two-point piercings.~~ means any transdermal or subdermal object that is embedded into a person's body. Implants do not include microdermal anchors or two-point piercings.

(16) through (29) remain as proposed, but are renumbered (17) through (30).

(31) "Subdermal object" means an item that is being, living, used, or made under the skin.

(30) through (33) remain as proposed, but are renumbered (32) through (35).

(36) "Transdermal object" means an item that is passed, entered, or made by penetration through the skin. Transdermal objects do not include microdermal anchors.

(34) through (36) remain as proposed, but are renumbered (37) through (39).

AUTH: 50-48-103, MCA

IMP: 50-48-102, 50-48-103, MCA

37.112.109 WATER SUPPLY (1) remains as proposed.

(2) A nonpublic water supply system must meet the requirements of Food and Consumer Safety (FCS) Circular 1-2012 when:

(a) the water supply is constructed after the effective date of this rule;

(b) modifications are made to the water system; or

(c) the local health authority determines compliance with FCS Circular 1-2012 is necessary to meet the requirements of this subchapter.

(2) through (9) remain as proposed, but are renumbered (3) through (10).

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

37.112.117 WORK ROOM REQUIREMENTS (1) through (7) remain as proposed.

(8) The work rooms must have a handwashing facility unless there is a handwashing facility outside the work room within ten feet of the work room door.

(a) remains as proposed.

(b) The handwashing ~~station~~ facility cannot be in the same room as the toilet.

(c) through (12) remain as proposed.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

37.112.131 STERILIZATION OF EQUIPMENT AND JEWELRY (1) and (2) remain as proposed.

(3) Whenever an autoclave is used, the following requirements apply:

(a) through (c) remain as proposed.

(d) Monthly biological monitoring must be conducted on the autoclave using standard spore units that are analyzed by a certified laboratory. The results of the ~~testing must be provided to the health authority on a monthly basis and the monthly spore test must be posted in a conspicuous place.~~

(e) The department or its designee may require that an operator submit the results of a monthly spore test directly to its office if the establishment fails to perform a monthly spore test or has one or more failed spore tests.

(e) and (f) remain as proposed, but are renumbered (f) and (g).

(4) remains as proposed.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

37.112.133 SKIN PREPARATION, ASEPTIC TECHNIQUE, AND AFTERCARE (1) and (2) remain as proposed.

(3) Before and after performing the tattooing or body piercing procedure, artists must remove all rings and then thoroughly wash their hands, wrists, and lower arms in warm running water with soap for at least 20 seconds, scrubbing around and under their fingernails, rinsing completely, and drying with clean, individual, disposable towels.

(4) Artists must wear a clean outer garment. A hair restraint must be worn if necessary to prevent the artist's hair from contact with the client. All necklaces, bracelets, or other personal items of the artist either must be removed or covered by the outer garment ~~or sterile gloves~~ to prevent the item coming in contact with the client.

(5) remains as proposed.

(6) If the artist wore gloves to wash or shave the client's skin, the artist must discard those gloves after completing those tasks. The artist must then remove gloves, wash hands, and put on a new pair of gloves before continuing the procedure.

(7) remains as proposed.

(8) If it is necessary to use a marking device, ~~the tip of the marking device must be vigorously wiped with 70% alcohol or other approved disinfectant before and after use, or used only once~~ the marking device will be used only once and disposed of or it must be autoclaved between uses.

(9) remains as proposed.

(10) If the artist's gloved hands become contaminated during the tattooing or body piercing procedure, then the artist must remove gloves, wash hands, and put on a new pair of gloves ~~rewash hands and reglove~~ before resuming the procedure.

(a) through (11) remain as proposed.

(12) Upon completion of the tattooing or piercing procedure, artists must apply an antiseptic solution to the procedure area with a clean single-use cotton ball, gauze, or tissue. In the case of a tattoo, the artist must then apply a sterile absorbent bandage to the tattooed site.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

37.112.147 TRAINING (1) Operators and artists must complete formal training ~~provided by the department or its designee that includes in~~ at least general sanitation, first aid, and universal precautions for preventing the transmission of blood-borne pathogens before licensure. Training may be provided by the department, its designee, or an organization approved by the department or its designee as having adequate content in each subject.

(2) remains as proposed.

(3) Guest artists and new artists must complete formal training and provide the inspecting authority with documentation of this training prior to working in a licensed facility. ~~Guest artists must also provide documentation of experience to the body art health authority in the jurisdiction they wish to work.~~

(4) and (5) remain as proposed.

AUTH: 50-48-103, MCA

IMP: 50-48-103, MCA

4. The department has thoroughly considered the comments and testimony received. A summary of the comments received and the department's responses are as follows:

COMMENT #1: One commenter stated that the definition of body modification is "ambiguous" and asked if it includes "altering hair, bodybuilding, dieting, etc.."

RESPONSE #1: The department agrees that the practices of altering hair, body building, and dieting would be considered body modification under this definition. Due to the explicitness of the way the term is used in the rule the department does not think it will result in confusion, because tattooing, body piercing, and ear lobe piercing are clearly defined and the restricted forms of body modification are explicitly outlined.

COMMENT #2: One commenter asked for clarification as to what the reasoning was for the 8mm length characteristic in the definition of transdermal and microdermal anchors.

RESPONSE #2: Research by the department at the time of rule writing found that 8mm includes all of the jewelry marketed as microdermal anchors while distinguishing microdermal anchors from larger transdermal anchors.

COMMENT #3: One commenter requested that the department clarify the reason for omitting the use of self-closing doors on bathrooms.

RESPONSE #3: Research by the department could not find that installing self-closing doors increased the safety of artists or their clients. As a result, the requirement was removed.

COMMENT #4: A number of commenters stated that the changes to ARM 37.112.131(2)(d) would result in either an undue burden being placed on licensed body art establishments or an increase in workload to local health departments that they would not be able to meet.

RESPONSE #4: The department agrees with the commenters. The department has reworded (2)(d) so that submission of spore test results to the department or its designee can be an optional requirement determined by the department or its designee based on whether an establishment fails to perform the necessary monthly autoclave spore tests or has one or more failed spore tests as determined during regular inspections.

COMMENT #5: A number of commenters suggested that in ARM 37.112.147(1) training may be appropriately provided by options other than the department or its designee.

RESPONSE #5: The department agrees there are a number of training options available to artists. It is unnecessary for the department or its designee to provide first aid and blood borne pathogen prevention training and this will be reworded by the department.

COMMENT #6: A number of commenters thought that "documentation of experience" in ARM 37.112.147(3) was vague or not under the purview of the health authority.

RESPONSE #6: The department agrees with the commenters and will remove this requirement from the rule.

COMMENT #7: One commenter said that the definition for the term implant in ARM 37.112.103 is too broad and that it contradicts itself.

RESPONSE #7: The department agrees with the commenter and has changed the definition of implant.

COMMENT #8: Two commenters did not like the changes to ARM 37.112.133(8). One commenter felt that the use of the term "vigorous" was too subjective to be in rule. The other commenter felt that the procedure to use 70% alcohol to clean a marking device is not adequate to prevent the spread of pathogens between clients.

RESPONSE #8: The department agrees with the second commenter and will remove this procedure from the rule.

COMMENT #9: A commenter found ARM 37.112.147(2) to be too wordy.

RESPONSE #9: The department disagrees with this assessment and will leave (2) as written.

COMMENT #10: A commenter requested that the term "cleaning room" be defined.

RESPONSE #10: The department agrees that this term needs to be defined. The department has added the definition.

COMMENT #11: A commenter has requested that the department adopt the Food and Consumer Safety (FCS) Circular 1 and add it to the current water supply section in ARM 37.112.109.

RESPONSE #11: The department agrees and has incorporated FCS Circular 1 into the rule.

COMMENT #12: A commenter requested that the wording in ARM 37.112.117(8)(b) be changed from "handwashing station" to "handwashing facility" so that terms are used consistently throughout the rule.

RESPONSE #12: The department agrees and has changed the term.

COMMENT #13: A commenter requested language be added to ARM 37.112.133 to explicitly state that equipment be changed out between clients.

RESPONSE #13: The department disagrees. In ARM 37.112.131(1) it is required that all nondisposable instruments be autoclaved and individually wrapped. In ARM 37.112.131(4) it states that sterile packages must be opened in full view of the client. In practice this means that an artist must change out equipment between clients.

COMMENT #14: A commenter has requested that the rule explicitly state in ARM 37.112.133(4) that rings be removed during the hand washing procedure.

RESPONSE #14: The department agrees and will make this change to the rule.

COMMENT #15: A commenter requested the department remove the word "sterile" to describe gloves in ARM 37.112.133(4).

RESPONSE #15: The department agrees and will make this change to the rule.

COMMENT #16: A commenter requested that the second sentence in ARM 37.112.133(6) be changed from "The artist shall then put on a new pair of gloves before continuing the procedure" to "The artist must then remove gloves, wash hands, and put on a new pair of gloves before continuing the procedure." Similar language regarding glove removal and hand washing was requested to be added to ARM 37.112.133(10).

RESPONSE #16: The department agrees and will make this change to the rule.

COMMENT #17: A commenter requested that the department require all artists to undergo drug testing in order to operate legally in Montana.

RESPONSE #17: The department does not have the authority to require drug testing of artists.

COMMENT #18: A commenter requested that the department add a requirement in ARM 37.112.133(12) to require absorbent sterile bandages be applied after antiseptic ointment is applied to a new tattoo.

RESPONSE #18: The department agrees and will add this language to the rule.

COMMENT #19: A commenter requested that ARM 37.112.137 be rewritten so that the meaning of infectious waste is more clear to both inspectors and operators.

RESPONSE #19: Infectious waste is defined in 75-10-1003, MCA with clarification from the Department of Environmental Quality. The department will provide DEQ's clarification through our web site and plan review application.

COMMENT #20: A commenter has requested that the wording "or designee" be added after the word "department" in ARM 37.112.159(1).

RESPONSE #20: The department disagrees that the word designee be added to the rule because 50-48-203, MCA allows local jurisdictions to write their own body art rules and conduct their own licensing. A local jurisdiction has the authority to do this and in so doing grant their own variances. When the department is responsible for the licensing of an establishment the department must also be responsible for approving variances to that license.

COMMENT #21: A commenter requested that ARM 37.112.163(5) and (6) be moved to ARM 37.112.133 so that tattooing process requirements are located together.

RESPONSE #21: The department agrees with this recommendation, however changes were not proposed to ARM 37.112.163 during the revision so the department cannot make changes to it during the comment period.

COMMENT #22: A commenter has requested that the department specifically prohibit the use of dermal punches in piercing procedures.

RESPONSE #22: Regulating the use of medical instruments is outside the authority of this rule.

COMMENT #23: A commenter has requested that restrictions of the use of single-use presterilized ear piercing equipment to the outer edge of the ear be removed in ARM 37.112.103(11) and ARM 37.112.167(1).

RESPONSE #23: These sections of the rule make no such restriction.

COMMENT #24: A commenter has requested that the department incorporate a skills test into the licensure requirements of the body art rule.

RESPONSE #24: The department is not qualified to determine the skill of licensees. The department can only make a determination on an individual's use of techniques that limit the spread of pathogens between individuals or cause infection in the individual receiving the work.

COMMENT #25: A commenter has requested that inspectors be required to receive training in body art before doing inspections.

RESPONSE #25: This comment is not pertinent to the current rule revision but the department will take this comment under advisement.

COMMENT #26: A commenter has requested that the department make the public more aware that they can make complaints about artists to the department or its designee.

RESPONSE #26: This comment is not pertinent to the current rule revision but the department will take this comment under advisement.

COMMENT #27: A commenter has requested wording be added to the rule that restricts the sale of tattooing equipment to individuals working outside of a licensed establishment.

RESPONSE #27: Restricting the sale of tattooing equipment is not within the department's authority.

/s/ Shannon L. McDonald  
Rule Reviewer

/s/ Richard H. Opper  
Richard H. Opper, Director  
Public Health and Human Services

Certified to the Secretary of State January 22, 2013